

# A Case of Illegal Agro-chemical Experimentation Without Informed Individual Consent on Maui and Molokai

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## Physicians Coalition for Responsible Agriculture on Maui

**PCRAM** is a coalition of health-minded medical doctors and all allied health professionals and citizens of the world supporting healthful, non-toxic, non-GMO, non-experimental, organic, permaculture agriculture on the Hawaiian island of Maui. Please join us in recruiting new members and supporting our causes of stopping agro-chemical experimentation without informed individual consent and of promoting healthful agriculture practices on Maui.



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## Primary Principle

To safeguard the public's health and respect individuals' rights, we do not want to allow exposure of unknown (experimental) harm to individuals without their informed consent. This has been happening for longer than a decade as experimental genetically modified organism (GMO) agro-chemical testing conducted by Monsanto has resulted in pesticide chemicals drifting and flowing into Maui's and neighboring island Molokai's communities with unknown health effects. The potential harm from pesticide drift and polluted overland runoff and groundwater infiltration from these activities is the issue in question. In principle, this is ethically wrong because it knowingly violates individuals' rights to choose to be free of the risks of such experimental activity.

## Terminologies

It is necessary to clearly understand the meanings of the germane terms and compare this issue to other past examples. For example, what did we do when we did not fully know the harm of cigarettes, second-hand cigarette smoke, flu vaccines, disinfectants in public drinking water, and prisoners on death row who need a "better" lethal injecting drug that causes less suffering?

## What Does "Experimental" Mean?

"Experimental" means unknown. This can be unknown benefits and unknown harm. Some public health interpretations compare potential benefits to risks. There may be a different risk-benefit ratio for each different type of individual (children, asthmatics, elderly, etc.). Many experiments are great—they turn out well. This is what moves medical science forward. However, proof of success after an experiment is over is never an excuse for not having obtained informed consent from individuals prior to the start of the experiment. This kind of hindsight argument is not valid since there are many examples when things did not turn out well. Test subjects must be fully informed of the risks and given the opportunity to opt-out. Even when things do turn out well, without prior informed consent, the project and those associated with it are unethical.

# What Does “Informed Consent” Mean?

## “Informed” Defined

“Informed” means explaining at an eighth grade level of understanding the risks (potential and known), benefits (potential and known), the actual experiment activity (randomized, controlled or blinded), and how subjects will be monitored under both good and bad outcomes. When something is not fully known (e.g., health effects of mixtures of chemicals, or distances that drift will occur and produce health effects), subjects must be told how much we do know, and how we know this. Another key disclosure is the individual’s alternatives to not participating in the experiment. This can be specific to (1) the subject (e.g., he will be given standard care with no retaliation for non-participation, etc.) or (2) to society in general (e.g., there may or may not be alternative drugs, each with their own good and bad points— toxicity, cost, ease of administration). Finally, there is disclosure of the sponsoring agencies, who must be readily available at any time to answer questions to prove that the experiment’s information is valid and that the experiment’s guidelines are followed.

## “Consent” Defined

“Consent” by each individual who participates in experiments must be given freely and in private. The experiment information can be provided en masse; however, questions must be allowed to be raised in private by each individual. Records must be kept of those who participate and those who decline. Records of whether or not a person participated should be kept private, but sometimes this is impossible. There must be no enticement or coercion (retaliation) directly or indirectly based on participation. It must be clearly stated that once subjects have entered an experiment, they can freely choose to quit at any time for any reason.

## Experiment Considerations

Even before seeking informed consent to enroll subjects, the whole experimental process (including informed consent procedures) must be approved and monitored for compliance. This is the role of Institutional Review Boards (IRB). Experimental activities which do not submit for IRB approvals cannot argue that they do not have IRB “disapproval” and they are, therefore,

ethical. On the other hand, IRBs cannot claim that they only review what is formally submitted to them. If an IRB hears of a questionable unethical experiment, it is obliged to follow through with its formal assessment, otherwise, unethical experiments would be conducted by simply skirting the IRB application process.

## **Institutional Review Board Oversight**

Oversight of experiments performed on any world citizen must be carried out by an Institutional Review Board (IRB) of the sponsoring agency(s) and/or by a community IRB to review all activities. IRBs insure that the experiment information is valid and that the procedures will be adhered to by those in charge. In general, IRBs will determine (1) if the activity is ethical at all, (2) if the experiment's scientific merit outweighs the risks. If these criteria are met, then the IRB will determine whether or not an informed consent is needed on an individual basis.

IRBs must evaluate informed consent forms (when deemed necessary). If there are two levels of IRBs involved in a study, the approval of both are needed to proceed. In U.S. research circles, we used to argue that local IRBs should review first so as not be influenced by the decision of the higher IRB authority. There is the possibility of implicit enticement and/or coercion in the recruitment of potential subjects in such settings as prisons, military, elderly, refugees, etc. In such cases, it can be difficult for IRBs to assess informed consent procedures and determine if they are valid or not. IRBs will require the opportunity to review forms of those who refused to participate in experiments after being informed. IRBs will also conduct sample spot check interviews of those who consented in order to confirm that there was a true understanding of the experiment risks and potential benefits, and no coercion or enticement. Once a study is underway, an IRB will monitor those test subjects who have chosen to leave the study for any reasons, and periodic reports will be made to assess the experiment's safety. IRBs will also sample and spot check those who remain, to insure that they are free to leave for any reason.

It is possible that one can ethically conduct human experimentation without an IRB if one simply interprets and follows accepted ethical guidelines (i.e., the Nuremberg/Helsinki Accord). Conversely, an IRB which strays from international guidelines (perhaps due to political or

financial influence) can do more damage than good. As pointed out by the framers of the Helsinki Accord, there are numerous cases where regulatory bodies (including the courts) biased the judgement of ethics because of unintentional or intentional inappropriate arguments (e.g., national security, economic stability, advancement of science, tacit consent, etc.).

Yes, informed consent is very important. It is tantamount to the difference between organ trafficking and organ donation.

## Informed Consent Exceptions

Why is there no explicit informed consent requirement for some known potentially hazardous activities (e.g., smoking and drinking water systems), while there is a requirement for others (e.g., flu vaccines and cancer chemotherapy trials)?

### Example 1

If the safety or harm of an activity is known to a reasonable degree of certainty, then the activity is not an “experiment” and needs no informed consent. These are examples of “non-experimental” hazards: water boarding (other than individual variation of response), marketed products after clinical trials (such as Narcan for suspected opiate overdoses), over-the-counter drugs, and volcanic lava fumes emissions when downwind closer than a certain distance. Sometimes the effects are very bad, misused, and in and of themselves unethical, but they are known and do not fall under “experimentation.”

### Example 2

If a certain activity’s effects are unknown (or not known well enough), but a reasonable person has been informed of the risk AND can avoid exposure, then there is tacit agreement that those participating give “informed consent” and the others who don’t want to participate can simply avoid exposure. So, after intense public education there may be no need for informed consent in this situation. For example, first-hand cigarette exposure (but not second-hand smoking effects), lava emissions at greater than a certain distance, municipal drinking water additives when purer bottled water is available from another source (as in Flint, Michigan), and tourists

risk warnings for such events as lava flows, vog drifts, rough surf conditions and shark sightings at beaches. When people can avoid a situation of risk but the risk is not so obvious, then we should consider explicit informed consent. Examples are: vaccines, GMO food which “looks” like other foods (hindsight of claims of GMO food safety is no excuse for not having gotten upfront informed consent), drinking water with undisclosed additives, cancer chemotherapy, and invisible chemical exposure.

### **Example 3**

An interesting paradox occurs when (1) there is known harm (non-experimental) to some and unknown harm to others AND (2) a person cannot reasonably avoid exposure. This points to a case we have faced on Maui where sugarcane burn smoke drifts into the surrounding communities really affecting those close by and possibly affecting those farther away (after decades of practice, this will cease at the end of 2016, for economic rather than ethical reasons). This raises the question: should we be given the opportunity to give informed consent or should the sugarcane company just be ordered to stop the activity under the threat of suit for damages? There was a similar situation cited as an example of unethical conduct (“That Time Scientists Tested Sulfuric Acid on Prisoners for No Reason”: <http://io9.gizmodo.com/that-time-scientists-tested-sulfuric-acid-on-prisoners-1565474612>). In 1907 “negro prisoners” in Louisiana were openly experimented on to see how much sulfuric acid in their molasses they could tolerate. There was no attempt to hear their objections (consent) because “it would not do any good if they did.”

### **Example 4**

Another paradoxical case that the islands of Molokai and Maui face is of utmost concern: pesticide drift from nearby experimental agro-chemical fields. The question arises: If harm of chemical mixtures and drift at great distances is unknown (experimental), and people cannot avoid exposure (unlike distributing bottled water to families in Flint Michigan), then shouldn't each individual within any drift range be asked to either give informed consent or to opt out of exposure? If everyone gives valid informed consent, then the activity can continue. But if just one exposed person decides to avoid exposure, then the ethical thing to do is to stop the activity. One's right to have his/her choice respected in this decision is not overruled by the majority

decision, nor can it be nullified by legislative or judiciary bodies. Most absurd, in the context of the experimental setting, is the argument that others have the right be profitable at the expense of chemicals drifting to others.

Field researchers have been faced with similar situations where the majority have asked for a study when a few refused. When a testing agency could not respect the wishes of the few, the experiments were cancelled by the IRB. Obviously, the economic scale and potential economic value of the experiment should have no bearing on the ethical decision for the individual, especially when the economic advantage to the subject is minimal. One senses this wrong when there are great enticements offered to subjects to enter experiments.

## **The Legal Impermanence Issue**

We should bear in mind that the recent media, court and legislative wrangling to determine who has the authority to make decisions on experimental agro-chemical activities on Maui may have resulted in an ephemeral decision. For example, the Hawaiian county island of Kauai's previous precautionary GMO measures are now being reversed by a newly elected county council.

In all of this confusion we have forgotten the rights of the individuals to choose for themselves and their children. There is absolutely nothing like an informed, concerned, engaged community to police its own rules of ethical individual rights. Ironically, we also should not have blind faith in those who framed the rules of the Helsinki Accord. Bodies can change and become corrupted. But it was this body which codified, introduced and gained recognition of the rights of the individual regarding human experimentation.

## **Maui Opted Out**

The Maui County vote in 2015 to moratorium experimental GMO field practices was our de facto informed consent opt-in/opt-out exercise. We informed our legislators of our choice: to opt-out. During the campaign leading up to the vote, coercive (loss of jobs) and enticing (economic stimulus to the economy) arguments were made. Those tactics would not have been

allowed if an IRB had overseen this vote. Often those supporting the moratorium were accused of fear mongering—but fear, no matter how “unscientifically” based, is a valid personal reason for individuals to opt-out of experimentation. Voters freely chose what “science” they wanted to believe, if any. They voted confidentially, free of personal coercion or enticement. The opt-out vote prevailed despite coercive propaganda enticement from different sectors of the business community which made claims of economic damage and job loss.

In addition to the human risk, many voters were also concerned about the risk to the environment and to non-GMO crops. Whether or not these concerns would be “legitimized” by an IRB focusing on human risk is unknown. Issues were raised largely unfiltered.

In the end, the moratorium vote was ruled invalid after Monsanto took the case to federal judges who ruled that states have jurisdiction over pesticides and Federal Agencies have authority over experimental GMO field activities. The issue of individual ethics and risk of experimentation was not allowed to be raised. U.S. county, state and federal review bodies were made aware that pesticide drift constituted an experiment, but they chose to avoid this framework (ethics). In fact, some governmental officials have intentionally excluded arguments of human health risks.

## **Individual Rights Preside**

In matters of safeguarding the public’s health, we must always consider each individual’s point of view when deciding if his or her safety should be sacrificed for the greater good. It was wrong that the Nazi doctors during the Nuremberg trials tried to justify their experimental actions with their claims that medical knowledge gained from unethical experiments could benefit other Nazi soldiers and all future mankind. The claim of benefit is certainly true but the means of getting this knowledge was grossly unethical. The potential benefit is a wrong justification; in our world’s legal system, individual ethical rights come first. One has a “gut” feeling for the rights of the individual. It follows the Golden Rule. Are those in power deciding the fate of individuals just because they are in power? What if the roles were reversed?

# The Violation Of Our Individual Rights Is Clear

A good test to see if we are acting free of bias when applying the above ethical criteria is to change the parties involved. For example, suppose that an enemy regime is experimenting on our citizens (taken prisoner) for the sake of national security, as did Germany's Nazis. Then consider our own country's agencies or its private corporations experimenting on our own citizens for the intended purpose of increasing the world's food supply. Now ignore who runs the experiments and consider who are the subjects and what is the objective of the experiment. Some situations seem more unfair than others. However, under the guidelines of the Helsinki accord they all abuse individual rights if there is no informed consent.....and this is what is happening on Molokai and Maui.

## Mounting World Opinion

Our Hawaii situation regarding pesticide use on GMO experimental fields was raised at the Hague Tribunal where Dr. Pang presented our case in October of 2016. A ruling will be made in April of 2017. Our position has been accepted for presentation at the International Public Health Forum (to be held in Melbourne, Australia in May of 2017). To enforce this clear violation of our citizen's ethical rights and to uphold the county's and state's charge to safeguard the welfare of its people, we will ask the World Medical Association (who follows guidelines of the Nuremberg/Helsinki Accord) for a ruling on Maui's case of agro-chemical experimentation with regard to the ethics of this situation when framed as an "experiment," which it truly is.

Now and hereafter, this issue must be raised on a grassroots level and the agencies in charge will have to address these concerns and the World Medical Association's ruling. As always, we will put our faith in the opinion and actions of an engaged public.

Let this paper serve as a catalyst for public discussion and action. Our inalienable ethical rights, the integrity of U.S. health safeguard laws, and lives are at stake.



Please support our cause by joining the Physicians Coalition for Responsible Agriculture on Maui on Facebook and contacting us. <https://www.facebook.com/groups/100764643749895/>

For more information, please watch Dr. Pang's video: "Ethical Violations of Pesticide Use in Hawaii on Experimental GM Fields"

<https://www.youtube.com/channel/UCGCC6WKByX89-LZ7Swp7tg>



## About the Authors

**Lorrin Pang** (writing here as a private citizen) was born and raised in Honolulu. He was an honors graduate from Princeton University with a degree in Chemistry. He received M.D. and Master Public Health degrees from Tulane University (New Orleans). He holds a Board Certification in Preventive Medicine. Dr. Pang worked for 20 years with the U.S. Army's Walter Reed Overseas Research Laboratories, assigned to Bangkok, Rio de Janeiro and Geneva, developing drugs and diagnostics for tropical diseases. He was a consultant to the World Health Organization from 1985 to 2005 for tropical diseases. In the year 2000, Dr. Pang retired and moved to Maui taking the position of the District Health Officer. He has had approximately six dozen papers published in peer reviewed medical journals covering rabies, HIV, malaria, hepatitis E, and most recently dengue. From the years 2007 to 2009, Dr. Pang was selected to America's Best Doctors Listing (comprising 3% of our nation's physicians). Since 2013, he has worked (1) as a reviewer for research proposals for the U.S. Congress, (2) as a consultant to the DNDI (an international group developing drugs for neglected diseases), and (3) has been a visiting professor of medicine for Federal University of Brasilia. Contact: [panghi71@gmail.com](mailto:panghi71@gmail.com)

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